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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,996	02/28/2002	Brian Leyland-Jones	3298.1003-000	2676

21005 7590 12/01/2004

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EXAMINER

LEWIS, AMY A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,996

Applicant(s)

LEYLAND-JONES, BRIAN

Examiner

Amy A. Lewis

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 41-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/22/04 & 8/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Priority to U.S. Provisional Application 60/329,262 filed on February 28, 2001, is acknowledged. Amended claims 41-46 are pending in this action.

Restriction

Applicant's election of Group II (claims 41-46) and preliminary amendments to the claims, in the response to the restriction requirement filed on September 13, 2004, is also acknowledged. It is noted that claims 41-46 have been amended and claims 1-40 and 47-88 are withdrawn.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 41-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Ratain et al. (Cancer Research 1993, 53: 2304-2308).

Ratain et al. teach a method of metabolic phenotyping to individualize amonafide dosage. Ratain et al. determined the acetylator phenotype of cancer patients in need of amonafide therapy, using caffeine as the probe drug and urine as the biological sample. “Urinary concentrations of an acetylated (AAMU)³ and nonacetylated (1X) metabolite are determined by high-pressure liquid chromatography”; and the acetylator phenotype (slow, indeterminate, or fast acetylators) is based on the molar ratio of AAMU:IX. (See Acetylator Phenotyping, p. 2304). Dosage regimen of amonafide was individualized based on this phenotype, where the initial dose levels for slow, indeterminate, and fast acetylators were 375, 300, or 250 mg/m² (for 5 days), respectively. (See Amonafide Dosing, p. 2304).

2) Claims 41-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Wainer et al. (U.S. Patent 5,830,672).

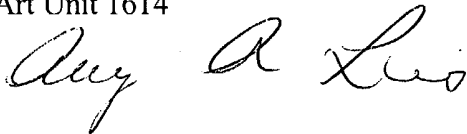
Wainer et al. teach a method for determining N-acetyltransferase (NAT2) phenotype using and enzyme linked immunosorbent assay (ELISA) kit to individualize therapy of drugs, including amonafide (col. 1, lines 8-14). The ELISA measures the molar ratio of caffeine metabolites in a urine sample (col. 3, lines 15-55; claims 1-3 and 5-10). The acetylation phenotype is based on this ratio, where patients with a ratio less than 1.80 are considered slow acetylators (col. 3, lines 55-58).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis
Patent Examiner
Art Unit 1614



Fred Krass
Primary Examiner
Art Unit 1614

